

Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)
Approved for use through xx/xx/200x. OMB 0651-00xx
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

GRA01236P00021US

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on **November 4, 2005**

Signature *Corinne Byk*

Typed or printed name **Corinne Byk**

Application Number

10/814,462

Filed

March 31, 2004

First Named Inventor

Patrick Antonelli et al.

Art Unit

3738

Examiner

Christopher D. Prone

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number **32,273**

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

F. William McLaughlin
Signature

F. William McLaughlin

Typed or printed name

(312) 876-1800

Telephone number

November 4, 2005


Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of **One** forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



Serial No. 10/814,462
GRA01236P00021US
PATENT

STATEMENT FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

Claims 30-39 are pending in the application, are rejected, and are at issue. Claims 30-35 and 37-39 are rejected as anticipated by Muller et al. U.S. Patent No. 6,537,199. Claim 36 is rejected as obvious over Muller et al. Claim 30 is the only independent claim.

Claim 30 specifies a self-crimping ossicular prosthesis comprising a pair of jaws of a bioactive material. Each jaw comprises a body having a semi-cylindrical inner surface for engaging opposite sides of an ossicle when implanted in a human ear, to anchor to the ossicle. A spring element of a flexible material, different from the pair of jaws, is operatively coupled to the jaws for biasing the jaws toward one another to provide clamping pressure. An actuator element is operatively coupled to the spring element.

Muller et al. in Fig. 6, and as discussed at col. 9, lines 12-30, discloses a device for mechanical coupling of a driver to a coupling site of the ossicular chain. The device includes a coupling element 35 in the form of a U-shape spring clamp to partially surround a coupling site 16 of the ossicular chain. An attenuator 34 is disposed between the coupling element 35 and the coupling site 16 to protect against damage. The attenuator is indicated to be of an entropy-elastic or rubber-elastic material, preferably a silicone resin. The purpose of the attenuator is otherwise generally described at col. 5, lines 11-56.

Muller et al. does not disclose or suggest any jaw, let alone a pair of jaws. It discloses a single U-shaped clamping element. The element alleged in the action to engage the ossicular chain, the attenuator, is not of a bioactive material or functional to anchor to the ossicle. Nor is there a spring element operatively coupled to jaws for biasing jaws toward one another to provide clamping pressure. As such, there is no anticipation and the rejection is improper.

The final action at page 2, references Muller et al. disclosing "a pair of jaws 34". Element 34 is a single element. It is not a pair of elements. It is formed as a piece of hose, i.e., cylindrical, which has been slit lengthwise. It is a single, cylindrical element. It is in the nature of a cylindrical sleeve with a slit to allow it to be placed surrounding part of the ossicular chain. The

final action at page 4 states that the upper and lower halves of element 34 comprise a pair of jaws. However, these are not distinct elements. To make them distinct elements would require slitting the attenuator to have two semi-cylindrical halves. Doing so would result in an inoperative device as it would not be self-retaining on the coupling site, as intended. As such, the claim limitation to a pair of jaws is not met by the reference and there is clear error in the rejection.

Claim 30 specifies that the jaws are of a bioactive material. A bioactive material elicits a favorable biological response to form a bond. The attenuator of Muller et al. is formed of an elastic material. To perform its function it must retain its elastic properties. There is no disclosure in Muller et al. that the attenuator is formed of a bioactive material. Nor does the action recite such disclosure. This is clear error. Moreover, the properties of the attenuator are to be elastic in nature. Forming a bond is contrary to this function. The formation of bonding would ultimately render the device non-elastic in nature so that the attenuator would not function for its intended purpose.

Moreover, the final action in the paragraph bridging pages 4 and 5 states that Muller “discloses that the jaws can be made of a bioactive ceramic material or silicone resin as admitted by the applicant”. There has been no such admission by applicant. This statement is clear error. Nor does Muller et al. teach that the attenuator can be made of a ceramic material. A ceramic material is not elastic in nature. As such, the limitation to jaws being of a bioactive material is not met by Muller et al.

Finally, Muller et al. does not disclose or suggest a spring element of a flexible material, different from a pair of jaws, operatively coupled to jaws for biasing the jaws towards one another to provide clamping pressure. If any element in Muller et al. corresponds to a pair of jaws it is the spring arms 36. However, the spring arms 36 are integral elements of the coupling element 35. There is no spring element of a different material to bias the spring clamps toward one another. The coupling element 35 comprises a unitary spring arm. It is pushed onto the attenuator to mount to the ossicular chain.

The coupling element is not coupled to the attenuator. It does not bias the attenuator toward one another (there is only one attenuator) to provide clamping pressure to anchor the attenuator to the ossicular chain. The attenuator retains itself on the ossicular chain, as does the coupling element. These elements function together differently from those claimed herein. The action at page 5 discusses element 36 as an elastic spring element coupled to a pair of jaws 34. There is no such coupling. The spring arms 36 are coupled to the coupling site 16 with the attenuator 34 providing an attenuating function therebetween. Thus, this limitation is not met by Muller et al.

The above limitations not being met, independent claim 30 is not anticipated by Muller et al. Nor does Muller suggest such limitations. Therefore, any obviousness rejection would be improper.

The remaining claims depend from claim 30. Claim 34 specifies that the spring element has opposite ends received in an opening in one of the jaws to provide swivel joints. The action at page 5 specifies that the spring arms 36 fit in a groove 35 on the coupling element 34 to allow the spring to pivot up and down. In fact, there is a groove 45 which prevents the spring arms from axially slipping off the attenuator, see col. 9, lines 44-46. The action mischaracterizes the reference. This is clear error. Moreover, the interpretation to Muller et al. disclosing a pivot joint is inconsistent with the statements that the materials of Muller et al. are bioactive. The forming of a bond, as with a bioactive material, would prevent pivoting. In any event, there is no disclosure or suggestion of any pivot action.

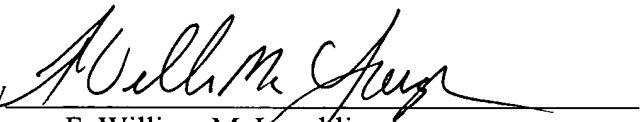
With respect to claim 35 which specifies that the swivel joint is surrounded by an elastomer, the action references Figs. 13, 14, 18-20 and 26-29 of Muller et al. as disclosing this feature. None of these figures illustrate a swivel joint, let alone a swivel joint surrounded by an elastomer. Instead, these embodiments disclose the attenuator being a coating on the coupling element.

Because Muller et al. does not disclose each and every element of claim 30, arranged as in the claim, there is no anticipation of any of the claims. Likewise, Muller et al. does not suggest the invention of any of claims 30-39.

For the above reasons, the rejection ought be reversed and the claims allowed.

Respectfully submitted,

Date: November 4, 2005

By 
F. William McLaughlin
Reg. No. 32,273

Wood, Phillips, Katz, Clark & Mortimer
Citigroup Center, Suite 3800
500 West Madison Street
Chicago, Illinois 60661-2511
Telephone (312) 876-1800
Facsimile (312) 876-2020